THIS OPINION WAS NOT WRITTEN FOR PUBLICATION

The opinion in support of the decision being entered today (1) was not written for publication in a law journal and (2) is not binding precedent of the Board.

Paper No. 40

UNITED STATES PATENT AND TRADEMARK OFFICE

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BEFORE THE BOARD OF PATENT APPEALS
AND INTERFERENCES

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Ex parte CANDANCE B. PERT
and MICHAEL R. RUFF

_____

Appeal No. 1996-0160
Application 07/898,691[1]

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HEARD: SEPTEMBER 14, 1999

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Before WILLIAM F. SMITH, ELLIS and ROBINSON, ***Administrative Patent Judges***.

ELLIS, ***Administrative Patent Judge***.

DECISION ON APPEAL

This is an appeal under 35 U.S.C. § 134 from the final rejection of claims 1 through 5, 7, 9 through 12, 14 through 17 and 19 through 22 and 24. Claims 6, 8, 13,

[1] Application for patent filed June 15, 1992. According to the appellants, this application is a continuation-in-part of Application 07/718,587, filed June 20, 1991, now abandoned; which is a continuation of Application 07/568,616, filed August 16, 1990, now U.S. Patent 5,276,016; which is a continuation of Application 07/314,507, filed February 15. 1989, now abandoned; which is a continuation of Application 07/048,148, filed May, 11, 1987, now abandoned; which is a continuation-in-part of Application 06/878,586, filed June 26, 1986, now abandoned; which is a continuation-in-part of Application 06/869,919, filed June 3, 1986, now abandoned.

18 and 23 have been canceled. Claim 1[2] is illustrative of the subject matter on appeal and reads as follows:

1. A method of treating tropical spastic paresis in mammals which comprise administering an effective amount of a peptide of the formula (I):

R^a-Ser-Thr-Thr-Thr-Asn-Tyr-R^b (I)

where R^a represents an amino terminal residue Ala-, D-Ala- or Cys-Ala- and R^b represents a carboxy terminal residue -Thr, -Thr-amide, -Thr-Cys or Thr-Cys-amide; or a peptide of formula (II):

R^1-R^2-R^3-R^4-R^5 (II)

where R^1 is an amino acid terminal residue XR^6 or R^6 wherein R^6 is Thr-, Ser-, Asn-, Leu-, Ile-, Arg-, or Glu- and X is Cys,

R^2 is Thr, Ser, or Asp,

R^3 is Thr, Ser, Asn, Arg, Gln, Lys or Trp,

R^4 is Tyr,

and R^5 is a carboxy terminal residue which is R^7X or R^7 wherein R^7 may be any amino acid and X is Cys or a physiologically acceptable salt thereof.

The references relied upon by the examiner are:

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[2] The claims before us were finally amended in Paper No. 33, filed October 11, 1995. We point out that there are two typographical errors which appear to have been overlooked by the appellants and the examiner. We direct attention to claim 3, line 2, which should read “an” effective blocking amount; and to claim 9, line 1, which should read “HTLV-I.” In the event of further prosecution of the application, these errors should be corrected.

Rudinger, "Characteristics of the Amino Acids as Components of a Peptide Hormone Sequence," ***Peptide Hormones***, University Park Press, Baltimore, MD, pp. 1-7 (1976).

Pert et al. (Pert), "Octapeptides Deduced from the Neuropeptide Receptor-Like Pattern of Antigen T4 in Brain Potently Inhibit Human Immunodeficiency Virus Receptor Binding and T-cell Infectivity," ***Proceedings of the National Academy of Sciences***, ***USA,*** Vol. 83, pp. 9254-58 (Dec. 1986).

Corbin et al. (Corbin), "Intranasal Peptide T Treatment in TSP/HAM: Preliminary Results of a Small Pilot Study," ***5th International Conference on Human Retrovirology***, Kamamoto, Japan, May 11-13, 1992 (Abstract).

The claims stand rejected as follows:[3]

I. Claims 1 through 5, 7, 9 through 12, 14 through 17 and 19 through 22 and 24 stand rejected under 35 U.S.C. § 112, first paragraph, as being based on a specification which fails to provide an enabling disclosure.

II. Claims 1 through 5, 7, 10 through 12, 15 through 17 and 20 through 22 stand rejected under 35 U.S.C. § 112, first paragraph, because the specification, as originally filed, does not provide support for (i) the "ester derivative in claims 2-3," and (ii) the phrase "R^7 may be any amino acid," set forth in claim 1.[4] Answer, p. 7.

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[3] The rejection of claims 1 through 5, 7, 9 through 12, 14 through 17, 19 through 22 and 24 under 35 U.S.C. § 103 as being unpatentable over Ruff, Pert, Buzy, Mayer, Bridge, or Heseltine alone, or optionally in view of Wu or Rodgers-Johnson I and Rodgers-Johnson II set forth on pp. 8-10 of the Answer (Paper No. 25), was withdrawn in the first supplemental Examiner's Answer (Paper No. 29). Accordingly, we have not addressed this issue in our decision.

[4] At oral argument, counsel for the appellants was not aware that this rejection was still pending in the application. We have carefully reviewed the examiner's Answer (Paper No. 25) and supplemental Answers (Paper Nos. 29 and 34) ; however, we do not find any indication that the rejection was withdrawn.

III. Claims 2, 7, 11, 16 and 21 stand rejected under 35 U.S.C. § 112, second paragraph, as being vague and indefinite.[5]

IV. Claims 1 through 5, 7, 9, 15 through 17 and 19 stand rejected under 35 U.S.C. § 102(a) as being anticipated by Corbin.

V. Claims 10 through 12, 14, 20 through 22 and 24 stand rejected under 35 U.S.C. § 103 as being unpatentable over Corbin.

We **reverse** Rejection I. We **affirm** Rejections II, III, IV and V. Our reasons follow.

Tropical spastic paresis (TSP) is a neurological disease caused by the human retrovirus HTLV-I. According to the appellants, the defining pathology for TSP is spasticity and limb weakness. Reply Brief, p. 12; Perk declaration (attachment to Paper No. 7), p. 9. Unlike AIDS, which is caused by the retrovirus HTLV-III, HTLV-I/TSP does not rapidly progress to death. That is, patients typically live for 30-40 years. Rodgers-Johnson I, p. 206.

The claimed invention is directed to a method of treating TSP in mammals using a peptide known as “Peptide T,” or specific fragments and analogues thereof. Peptide T, is so called, because of its high threonine content. Specification, p. 7. The amino acid

[5] At oral argument, counsel for the appellants was not aware that this rejection was still pending in the application. We have carefully reviewed the examiner’s Answer (Paper No. 25) and supplemental Answers (Paper Nos. 29 and 34); however, we do not find any indication that the rejection was withdrawn.

sequence is as follows: ala-ser-thr-thr-thr-asn-tyr-thr. ***Id***.

Rejection I

The examiner provides numerous reasons in the Answer and the supplemental Answers as to why the specification would not have enabled one skilled in the art to make and use the claimed method. As we understand it, the only remaining issue, in that regard, is whether the specification would have enabled such person to make and use the "broad range of tertrapeptides [sic, tetrapeptides] and pentapeptides" encompassed by the claims. Supplemental Answer (Paper No. 34), sentence bridging pp. 1-2. In brief, the examiner argues that

> the appellant should note that amino acid residues can be considered as members of different classes, that it is ***doubtful*** that the claimed pentapeptides and tertrapeptides [sic, tetrapeptides] with different lengths from peptide T would have similar activity, and that no data at all has been presented to show that such pentapeptides and tetrapeptides would have similar activity as the tested octapeptide. In view of the working examples, the nature of the invention, the state of the art, the unpredictability of the changes to amino acid sequences and the breadth of the claims, it would take undue experimentation to practice the invention as
> broadly claimed [emphasis added] [***Id.***, p. 2].

It is well established that the examiner may reject the claims as being based on a non-enabling disclosure when s/he has reason to conclude that one skilled in the art would be unable to carry out the claimed invention. ***In re Buchner***, 929 F.2d 660, 661, 18 USPQ2d 1331, 1332 (Fed. Cir. 1991); ***In re Marzocchi***, 439 F.2d 220, 223, 169 USPQ 367, 369 (CCPA 1971) ("a specification disclosure which contains a teaching of

the manner and process of making and using the invention in terms which correspond in scope to those used in describing and defining the subject matter sought to be patented ***must*** be taken as in compliance with the enabling requirement of the first paragraph of § 112 ***unless*** there is a reason to doubt the objective truth of the statements contained therein which must be relied on for enabling support").

We agree with the examiner that one skilled in the art would have generally expected that the substitution of one amino acid for another would alter the binding activity of a peptide to a receptor. However, the relevant issue, here, is whether such person would have expected the specific amino acid substitutions required by the claims to result in the production of a Peptide T analogue which would not be useful for the treatment of TSP. In the case before us, we find that the specification provides evidence that the core peptide, Peptide T, is useful for treating TSP patients. Specification, pp. 41-42. In addition, the Pert reference discloses that three analogues of Peptide T inhibit the binding of the gp120 protein of HTLV-III to brain membranes, ***in vitro***. Pert, the abstract. Although Pert is directed to the use of the analogues in an assay intended to test the efficacy of drugs for a different disease (AIDS), the reference, nevertheless, demonstrates that the biological activity of peptide T analogues is maintained when alterations are made in the amino acid sequence. Thus, in our view, the teachings of Pert would have suggested to those skilled in the art that Peptide T analogues, such as those set forth in the claims, would be useful for the treatment of TSP. Accordingly, since the evidence of record, does

not support the examiner's finding of nonenablement, the rejection is reversed.

Rejection II

According to the examiner, the specification, as originally filed, does not provide support for (i) the "ester" derivative set forth in claims 2 and 3, and (ii) the phrase "R^7 may be any amino acid," as set forth in claim 1. Answer, p. 7.

With respect to the ester derivative, the appellants acknowledge in their appeal brief (Paper No. 21) filed August 26, 1994, that "the phrase 'which is an ester or an amide' was inadvertently not deleted from claim 2," in their amendment filed under 37 CFR § 1.116. Brief (Paper No. 21), p. 15. Since the appellants and the examiner are in agreement that the phrase is improper, the rejection is affirmed.

As to the phrase "R^7 may be any amino acid," we find that the appellants point to p. 8, lines 19-20 of the specification for support. Brief (Paper No. 21), p. 15-16. We have reviewed the referenced section of the specification, but in our view the statement that R^5 may vary widely, does not to extend to amino acids at other positions. That is, we find that the specification speaks to the amino acid residue at the R^5 position itself, and not to when R^5 is R^7. Accordingly, the rejection is affirmed.

Rejection III

The examiner argues the recitation of the amide derivatives in claim 2, line 6 and the last line, is indefinite because "said amide derivatives would include the various amides already recited in the claim on lines 5 and 12-13." Answer (Paper No. 25), p. 7.

Again, the appellants acknowledge that "the phrase 'which is an ester or an amide' was inadvertently not deleted from claim 2," in their amendment filed under 37 CFR § 1.116. Brief (Paper No. 21), p. 16. Thus, since the appellants and the examiner are in agreement that the claim language is improper, the rejection is affirmed.

Rejections IV and V

As a preliminary matter we note that the examiner states that claims 1 through 5, 7, 9 through 12, 14 through 17, 19 through 22 and 24 "may only have the present filing date (June 15, 1992) as the effective filing date." Answer (Paper No. 25), p. 8. We understand the examiner's statement to mean that the effective filing date of the referenced claims ***is*** June 15, 1992. The appellants have not contested this date.

In the case before us, the examiner has rejected the claims over an abstract, dated May 11-13, 1992, and co-authored by Corbin, Ruff, and Rodgers-Johnson. Thus, since, on its face, the reference appears to have been published "by others," less than one year before the effective filing date of the present application, it is available as prior art under 35 U.S.C. § 102(a). However, since an applicant's ***own*** work within one year of the filing date of his patent application cannot be used against him under § 102(a), an applicant can have the publication removed as a reference by filing an affidavit which establishes that the relevant portions of the publication originated with, or were obtained from, him. To that end, the appellants have filed a declaration by Dr. Pert and Mr. Ruff, executed September 17, 1993, which they contend is an "***In re Katz***

declaration." Reply Brief (Paper No. 26), pp. 26-27; ***In re Katz,*** 687 F.2d 450, 215 USPQ 14 (CCPA 1982).

With respect to both prior art rejections, the sole issue before us, is whether the declaration of Dr. Pert and Mr. Ruff is sufficient to establish that the Corbin abstract, is their own work of and, thus, is not available as prior art against the claimed method. In turning to the declaration, we find that the declarants state that the Corbin abstract was authored by two people, Corbin and Ruff. Declaration, p. 1, para. 2. This is not correct. As we discussed above, the abstract was co-authored by three people, Corbin, Ruff and ***Rodgers-Johnson***. Since the declarants make no acknowledgment of Rodgers-Johnson with respect to her role on the abstract and the claimed subject matter, we find the declaration insufficient to remove the publication as prior art. Accordingly the rejection is affirmed.

The decision of the examiner is affirmed.

No time period for taking any subsequent action in connection with this appeal may be extended under 37 CFR § 1.136(a).

AFFIRMED

William F. Smith Administrative Patent Judge	)
Joan Ellis Administrative Patent Judge	) BOARD OF PATENT) APPEALS AND) INTERFERENCES
Douglas W. Robinson Administrative Patent Judge	)

JE/cam

William J. Sapone
Nims, Howes, Collison, Hansen and Lackert
650 Third Avenue
New York, NY 10158